



### General

#### Guideline Title

Cardiometabolic risk management guidelines in primary care.

### Bibliographic Source(s)

Guideline Developing Team. Cardiometabolic risk management guidelines in primary care. Qatif (Saudi Arabia): Qatif Primary Health Care; 2011. 124 p.

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Quality Improvement Team in Chronic Care (CCQI). Cardiometabolic risk management in primary care. Qatif (Saudi Arabia): Qatif Primary Health Care; 2008. Various p.

## Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• April 8, 2016 – Metformin-containing Drugs : The U.S. Food and Drug Administration (FDA) is requiring labeling changes regarding the recommendations for metformin-containing medicines for diabetes to expand metformin's use in certain patients with reduced kidney function. The current labeling strongly recommends against use of metformin in some patients whose kidneys do not work normally. FDA concluded, from the review of studies published in the medical literature, that metformin can be used safely in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function.

## Recommendations

## Major Recommendations

Note from Qatif Primary Health Care and National Guideline Clearinghouse (NGC): English is the main language of the guideline. However, many pages have been written in Arabic to facilitate their implementation by the users, especially nurses. These include recommendations related to lifestyle management and information management.

Cardiometabolic risk factors (CMR) encompass a cluster of modifiable classic and emerging risk factors and markers that identify individuals at increased risk for cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM). CMR includes factors that make up the definition of metabolic syndrome (MetSyn); in addition to four other factors: smoking, elevated low-density lipoprotein-cholesterol (LDL-C), inflammatory markers, and insulin resistance.

#### Cardiometabolic Risk

Metabolic Syndrome

- Abdominal obesity
- Elevated blood pressure (BP) (≥130/85)
- Elevated Fasting Blood Sugar (FBS) (≥110)
- Elevated serum triglycerides (S. Tg) (>150)
- Low high-density lipoprotein (HDL) (<40)

Elevated low-density lipoprotein (LDL) (≥130)

Smoking

Inflammatory markers

Insulin resistance

#### Clinical Highlights and Recommendations

- 1. Focus on cardiovascular risk (CVR) reduction (blood pressure control, statin use, aspirin [ASA] use, and tobacco cessation).
- 2. Self-management support is necessary for people with CMR to manage their disease.
- 3. Prevent microvascular complications through annual eye exams, foot risk assessments and foot care counseling, and annual screening for renal function.
- 4. Screen for renal function by more sensitive tools including albumin-creatinine ratio (ACR) and estimated glomerular filtration rate (eGFR).
- 5. Screen every individual >45 years of age and obese individuals for CMR factors.
- 6. Involve other community nurses (those involved in vital signs measurement and laboratory results) in chronic care.
- 7. Use clinical information to identify individuals at higher need of care.
- 8. Use quality indicators and electronic data management for monitoring the performance.
- 9. Build a nurse-led chronic care.
- 10. Offer multiple tools for assessing lifestyle and self-management.
- 11. Screen for depression.
- 12. Weight reduction is pivotal in managing cardiometabolic risk.

#### Screening

Obesity: Screening & Classification

- 1. Measure weight in each clinic visit.
- 2. Calculate body mass index (BMI) at least once each year (see the original guideline document for an example of how to calculate BMI and a BMI calculation chart).
- 3. Waist circumference should be measured, at least in overweight persons to better classify obesity (see table below). (To measure waist circumference locate the top of the hip bone. Place the tape measure evenly around the bare abdomen at the level of this bone. Read the tape measure and record the waist circumference in inches or centimeters.)

Table. Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risk\*

Obesity Class	BMI (kg/m <sup>2</sup> )	Disease Risk* (Relative to Normal Weight and Waist Circumference)		Action
		Men ≤40 in (≤102 cm)*** Women ≤35 in (≤88 cm)***	>40 in (>102 cm) >35 in (>88 cm)	
Underweight	<18.5	-	-	Advise for good lifestyle
Normal**	18.5–24.9	-	-	Advise for good lifestyle
Overweight	25.0–29.9	Increased	High	Advise for lifestyle change
Obesity I	30.0–34.9	High	Very high	Evaluate within 2 months
Obesity II	35.0–39.9	Very high	Very high	Evaluate within 2 months
Obesity III	≥40	Extremely high	Extremely high	Evaluate within 2 months

<sup>\*</sup> Disease risk for type 2 diabetes, hypertension, and CVD.

#### Hypertension: Screening, Classification & Diagnosis

- 1. Blood pressure (BP) should be measured in each visit to the clinic.
- 2. If an elevated blood pressure reading has been obtained, the blood pressure level should be rechecked.
- 3. Confirmation of hypertension (persistent high BP) is based on the initial visit plus two follow-up visits with at least 2 blood pressure readings at each visit, over a period of 1 to several weeks.

Table: Definitions, Classification and Actions of Blood Pressure Levels (mmHg)

Category <sup>A</sup>	Systolic	Diastolic	Action
Optimal	<120	<80	Advise for good lifestyle
Normal	120– 129	80–84	Advise for good lifestyle
High normal (Pre-Hypertension)	130– 139	85–89	Advise for lifestyle change
Grade 1 hypertension (mild)	140– 159	90–99	Evaluate and confirm within 2 months
Grade 2 hypertension (moderate)	160– 179	100– 109	Evaluate and confirm within 1 month
Grade 3 hypertension (severe)	≥180	≥110	Evaluate and treat immediately
Isolated systolic hypertension	≥140	<90	В
Hypertensive Urgency: Grade 3 HTN without signs of acute TOD	≥180	≥110	Evaluate and treat immediately
Hypertensive Urgency: Grade 3 HTN without signs of acute TOD	≥220	≥120	Evaluate, treat and consider admission
Hypertensive Emergency: <i>Grade 3 HTN with suspicious</i> signs of acute TOD	≥180	≥110	Evaluate, call ambulance, stabilize, treat immediately and refer immediately

Abbreviations: HTN, hypertension; TOD, target organ damage

<sup>\*\*</sup> Increased waist circumference can also be a marker for increased risk even in persons of normal weight.

<sup>\*\*\*</sup> These values have not been validated in Middle Eastern population.

<sup>&</sup>lt;sup>A</sup>When a patient's systolic and diastolic blood pressures fall into different categories, the higher category should apply.

<sup>B</sup>Isolated systolic hypertension can also be graded (grades 1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided diastolic values are <90 mmHg.

N.B.: Diabetic patients found to have repeat systolic blood pressure 130 mmHg or diastolic blood pressure 80 mmHg confirms a diagnosis of hypertension.

Diabetes Mellitus: Screening, Classification & Diagnosis

Criteria for testing for diabetes in asymptomatic adult individuals:

- 1. Testing for diabetes should be considered in all individuals at age 45 years and above, particularly in those with a BMI  $\geq$ 25 kg/m², and, if normal, should be repeated at 3-year intervals.
- 2. Testing should be considered at a younger age or be carried out more frequently in individuals who are overweight (BMI  $\geq$ 25 kg/m²) and have additional risk factors:
  - Are habitually physically inactive
  - Have a first-degree relative with diabetes
  - Have delivered a baby weighing ≥4 kg or have been diagnosed with gestational diabetes mellitus (GDM)
  - Are hypertensive (≥140/90 mmHg)
  - Have a high-density lipoprotein (HDL) cholesterol level <35 mg/dL (0.9 mmol/L) or a triglyceride level >250 mg/dL (2.8 mmol/L)
  - On previous testing, had impaired glucose tolerance (IGT), impaired fasting glucose (IFG) or glycated hemoglobin (A1c)≥5.7%
  - Have other clinical conditions associated with insulin resistance (e.g., polycystic ovary syndrome [PCOS] or acanthosis nigricans)
  - Have a history of vascular disease (e.g., stroke, coronary heart disease [CHD], peripheral vascular disease [PVD])

Table: Definitions, Classification and Actions of Blood Sugar Levels (mg/dL)

Category	Fasting Blood Sugar (FBS)	Oral Glucose Tolerance Test (OGTT)	Random Blood Sugar (RBS)	Alc	Action
Normal	<100 mg/dL (5.6 mmol/L)	<140 mg/dL (7.8 mmol/L)	A	<5.7%	Advise for good lifestyle
Pre-diabetes	100–125 mg/dL (5.6–6.9 mmol/L) (IFG)	140–199 mg/dL (7.8–11 mmol/L) (IGT)	A	5.7–6.4%	Advise for lifestyle change
Diabetes Mellitus					
Asymptomatic <sup>B</sup>	≥126 mg/dL <sup>B</sup> (6.9 mmol/L)	≥200 mg/dL <sup>B</sup> (11 mmol/L)	≥200 mg/dL <sup>B</sup> (11 mmol/L)	≥6.5% <sup>B</sup>	Evaluate and confirm within 1 week
Symptomatic <sup>C</sup>	≥126 mg/dL (6.9 mmol/L)	≥200 mg/dL (11 mmol/L)	≥200 mg/dL (11 mmol/L)	≥6.5%	Evaluate immediately
How Performed	Blood sugar is measured after at least an 8 hour fast (no caloric intake)	75-gram glucose load (drink) is ingested after at least an 8 hour fast; blood sugar is measured at 2 hours	Blood glucose is measured at any time regardless of eating	Blood glucose is measured at any time regardless of eating	

ANot appropriate for ruling out diabetes mellitus (DM).

<sup>&</sup>lt;sup>B</sup>Test must be confirmed by repeating on a different day.

<sup>&</sup>lt;sup>C</sup>The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss.

The American Diabetes Association endorse the use of A1c of 6.5% or higher as the primary criterion for the diagnosis of diabetes. However, the use of A1c for the diagnosis of diabetes has several limitations. These are:

- It is not recommended for diagnosing DM-I or gestational DM.
- It may be misleading in the setting of various hemoglobinopathies, iron deficiency, hemolytic anemias, thalassemias, spherocytosis, and severe hepatic and renal disease. Review page 66 of the original guideline document for further details.

#### Dyslipidemia: Screening, Classification & Diagnosis

- 1. Complete lipoprotein profile (total cholesterol, serum triglycerides, LDL and HDL) must be obtained after 9- to 12-hour fast.
- 2. Keeping tourniquet in place longer than 3 minutes may cause 5% variation in lipid values.
- 3. If lipid measurement is high, one more measurement should be taken prior to classifying risk, initiating drug treatment or starting an intensive lifestyle treatment.
- 4. If the total cholesterol level varies more than 30-40 mg/dL (1 mmol/L) in the two measurements, a third measurement should be taken and the average of the three measurements should be used as the baseline measure.
- 5. Diagnosis and reason for re-test have to be noted on the lab request.

Table: Definitions, Classification and Actions of Blood Cholesterol Levels in mg/dL (mmol/L)

Category	Level	Action		
LDL Cholesterol (Primary Target of Therapy)				
Optimal	<100 (2.5)	Advise for good lifestyle		
Near optimal/above optimal	100-129 (2.5-3.3)	Advise for good lifestyle		
Borderline high	130-159	Advise for lifestyle change		
• High	160-189	Evaluate and confirm within 2 months		
Very high	≥190	Evaluate and confirm within 2 months		
Total Cholesterol				
Desirable	<200	Advise for good lifestyle		
Borderline high	200-239	Advise for lifestyle change		
• High	≥240	Evaluate and confirm within 2 months		
HDL Cholesterol				
Low (abnormal)	<40	Evaluate and confirm within 2 months		
• High	≥60	Advise for good lifestyle		

- 1. Individuals at age of 45 years and over (preferably, at age of 35 for male)
- 2. All obese individuals
- 3. All hypertensive, diabetic and dyslipidemic individuals

#### Repeat CVR Assessment

- Each 10 years for low risk individuals
- Each 5 years for intermediate risk individuals
- Annually for high risk individuals, hypertensive, diabetic and dyslipidemic individuals

Use CMR Encounter Form no. 1 (CMR1, available in the original guideline document) to help you in the assessment.

Aim

To identify individuals at high risk to develop CVD. These include individuals with DM, hypertension, hypercholesterolemia, morbid obesity and multiple risk factors for CVD.

Rationale

Early detection and intervention help to reduce morbidity, improve quality of life and lower cardiovascular (CV) mortality.

#### How

- 1. Take history of:
  - a. Sedentary lifestyle (assess level of exercise)
  - b. DM, hypertension (HTN), dyslipidemia and vascular disease
  - c. Smoking
- 2. Is there a family history of premature cardiovascular disease/death (age Male <55; Female <65 years)
- 3. Measure:
  - a.  $BMI \pm waist$  circumference
  - b. BP
  - c. Fasting blood sugar (FBS) and lipid profile
- 4. Stratify CVR risk:
  - Management of hypertension, hypercholesterolemia and obesity are related to the quantification of total CV risk (i.e., the chance to
    develop a major CV event [stroke or MI] in 10 years.) (See the original guideline document for stratification and definitions of CV
    risk.)

#### Assessment

Assessment of Obesity

This assessment has to be done in the initial and the total assessment visits.

Assessment helps in finding answers to:

- 1. What is the class of the obesity?
- 2. What other CV risk factors does the patient have?
- 3. What is the risk to develop CVD?
- 4. Is there any comorbid condition? (e.g., depression, eating disorders, sleep apnea, arthritis, and use of medication)
- 5. Is it a secondary obesity?
- 6. How much does the obesity affecting the individual's quality of life? (e.g., mobility, self-esteem, socialization)
- 7. Discuss lifestyle.
- 8. Discuss environmental, social and family factors, including family history of obesity and co-morbidity.
- 9. Is the individual aware of the health consequences of obesity, and benefits of treatment?
- 10. Was there any attempt to lose weight? Why not effective?
- 11. Is the individual ready to start change?
- 12. Is the individual a candidate for medication therapy or surgical interventions?

#### 13. Is there any indication for specialist referral?

#### Classify Obesity

Waist circumference should be measured, at least, in overweight persons to better classify obesity. (See the table, "Classification of Overweight and Obesity by BMI, Waist Circumference, and Associated Disease Risk" above.)

#### Binge-eating Disorder Questionnaire

Referral for specialist psychological assessment should be considered where binge-eating disorder is suspected and the patient answers "Yes" to all of the following four questions:

- 1. Are there times during the day when you could not have stopped eating, even if you wanted to?
- 2. Do you ever find yourself eating unusually large amounts of food in a short period of time?
- 3. Do you ever feel extremely guilty or depressed afterwards?
- 4. Do you ever feel more determined to diet or to eat healthier after the eating episode?

#### Secondary Causes of Obesity

- 1. Hypothyroidism
- 2. Cushing syndrome
- 3. Insulinoma
- 4. Hypothalamic obesity
- 5. Polycystic ovarian syndrome
- 6. Genetic syndromes (e.g., Prader-Willi syndrome, Alström syndrome, Bardet-Biedl syndrome, Cohen syndrome, Börjeson-Forssman-Lehmann syndrome, Fröhlich syndrome)
- 7. Growth hormone deficiency
- 8. Oral contraceptive use
- 9. Medication-related (e.g., phenothiazines, sodium valproate, carbamazepine, tricyclic antidepressants, lithium, glucocorticoids, megestrol acetate, thiazolidinediones, sulphonylureas, insulin, adrenergic antagonists, serotonin antagonists [especially cyproheptadine])
- 10. Eating disorders (especially binge-eating disorder, bulimia nervosa, night-eating disorder)
- 11. Hypogonadism
- 12. Pseudohypoparathyroidism

#### Diagnostic Evaluation of Obese Patient

All obese patients	<ul> <li>BP measurement &amp; heart rate</li> <li>FBS and lipid profile</li> <li>Thyroid-stimulating hormone (TSH)</li> <li>Liver and renal function tests</li> </ul>
Suspected Obstructive Sleep Apnea (daytime sleepiness, loud snoring, gasping or choking episodes during sleep and awakening headaches)	<ul> <li>Measurement of neck circumference (&gt;17 inches in men, &gt;16 inches in women)</li> <li>Polysomnography for oxygen desaturation, apnea and hypopneic events</li> <li>Ears, nose, and throat (ENT) examination for upper airway obstruction</li> </ul>
Suspected Alveolar Hyperventilation (Pickwickian) syndrome (hypersomnolence, right sided heart failure including elevated JVP, hepatomegaly and lower limb edema)	<ul> <li>Polysomnography (to rule out obstructive sleep apnea)</li> <li>Complete blood count (CBC) to rule out polycythemia</li> <li>Blood gases (PCo<sub>2</sub> often elevated)</li> <li>Chest X-ray (enlarged heart and elevated hemidiaphragm)</li> <li>Electrocardioigram (ECG): right atrial and right ventricular enlargement</li> </ul>

	Pulmonary Function Test: reduced vital capacity and respiratory reserve volume
Suspected Hypothyroidism	• TSH
Suspected Cushing's syndrome (moon face, thin skin that bruise easily, severe fatigue, striae)	<ul> <li>Elevated late-night salivary cortisol level (&gt;7.0 nmol/L diagnostic, 3.0-7.0 nmol/L equivocal)</li> <li>Repeatedly elevated measurements of cortisol secretion (late night salivary cortisol or urine free cortisol, upper normal 110-138 nmol/dL)</li> </ul>
Suspected Polycystic Ovarian Syndrome (oligomenorrhea, hirsutism, enlarged ovaries may be palpable, hypercholesterolemia, impaired glucose tolerance, persistent acne and androgenic alopecia)	Morning blood draw for total testosterone, free and weakly bound testosterone, Dehydroepiandrosterone sulfate (DHEAS), prolactin, TSH and early morning 17- hydroxyprogesterone

See the original guideline document for the table, "Medications that interfere with weight loss or induce weight gain."

Assessment of Patient Readiness to Lose Weight

- 1. Determine patient's interest and confidence. See the original guideline document for self-assessment tables rated 1 to 10 for:
  - How important is it for you to lose weight at this time?
  - How interested are you in losing weight at this time?
  - How confident are you to lose weight at this time?
- 2. Ask targeted questions:

Aim to gain more information about the patient and to involve her/him in a self-reflection process that may facilitate readiness to change, e.g.:

- What is hard about managing your weight?
- How does being overweight affect you?
- What cannot you do, now, that you would like to do if you weigh less?

#### Stages of Change Model to Assess Readiness to Lose Weight

See the original guideline document for a diagram of the stages of change model to assess readiness to lose weight and a table on applying the stages of change model to assess readiness to lose weight.

#### Assessment of Hypertension

- 1. This assessment has to be done in the initial and the annual assessment visits. It might be repeated as needed.
- 2. Use CMR Encounter Form no. 2 (CMR-2, available in the original guideline document) to help in the assessment.

#### Assessment Helps in Finding Answers for

- 1. What is the level of the BP?
- 2. Is it a secondary HTN?
- 3. What other CV risk factors does the patient have?
- 4. Is there any complication (target organ damage [TOD])?
- 5. What is the current management, if any?
- 6. How is the quality of life?
- 7. What is the risk to develop CVD?

#### Medical History

- Duration and previous level of high BP
- Previous admissions and visits to the emergency room (ER)

- History of target organ damage (sub-clinical TOD/cardiovascular or renal disease [CVRD])
- Symptoms of TOD:
  - Brain and eyes: headache, vertigo, impaired vision, transient ischaemic attacks, sensory or motor deficit
  - Heart: palpitation, chest pain, shortness of breath, swollen ankles
  - Kidney: thirst, polyuria, nocturia, hematuria
  - Peripheral arteries: cold extremities, intermittent claudication
- Risk factors for CVD
- Lifestyle (including amount of physical exercise, dietary habits and psychosocial factors that might influence the management of hypertension)
- Previous antihypertensive therapy: drugs used; efficacy and adverse effects; herbs and other traditional therapy
- Use of other medications that might raise the BP
- Features of secondary hypertension
- · History of snoring and sleep apnea
- Family history of HTN, premature CVD, premature sudden death (males <55; females <65 years), and chronic kidney or endocrine diseases

#### Physical Examination

- Measure BP correctly (2 or more BP measurements separated by 2 minutes with the patient seated)
- Measure BP after standing for at least 2 minutes, in elderly and diabetic patients.
- Verify in the contralateral arm; if values are different, the higher value should be used.
- Measure BMI and waist circumference
- Look for signs of TOD
  - Brain: murmurs over neck arteries, motor or sensory defects, gait and cognition
  - Retina: refer to ophthalmology for fundoscopic abnormalities
  - Heart: location and characteristics of apical impulse, abnormal cardiac rhythms, ventricular gallop, pulmonary rales or bronchospasm, dependent edema
  - Peripheral arteries: diminished or absent peripheral arterial pulsations, carotid bruits, radio-femoral pulse delay and edema; cold extremities and ischaemic skin lesions
- Look for features of secondary hypertension. (See the table, "Secondary Hypertension: Causes and Clinical Features" in the original guideline document.)
- In suspected white-coat HTN (WCH), use home BP measurement (HBPM) or refer the patient for ambulatory (24-hr) BP measurement (ABPM). Please note that cut-off values for high BP are, in these measurements, different from clinic-based values.

#### Laboratory Work-up

- · Fasting blood sugar
- Lipid profile (total cholesterol, LDL, HDL and serum triglycerides)
- Serum creatinine and eGFR
- Serum potassium and sodium
- Urinalysis
- Serum uric acid
- Hemoglobin and hematocrit
- Electrocardiogram
- Microalbuminuria

#### Assessment of Diabetes Mellitus

- This assessment has to be done in the initial and the annual assessment visits. It might be repeated as needed.
- Use CMR Encounter Form no. 2 (CMR-2, available in the original guideline document) to help in the assessment.

#### Assessment Helps in Finding Answers for

- 1. What is the type of DM?
- 2. Is it secondary?
- 3. What are the other CVD risk factors the patient has?
- 4. What are the complications he has?
- 5. What is the current management, if any?

- 6. Is his DM controlled?
- 7. How is his quality of life?
- 8. What is the risk to develop CVD?

#### Medical History

- 1. Symptoms and results of laboratory tests
- 2. Current treatment of diabetes, including medications, meal plan, and results of glucose monitoring
- 3. Frequency, severity, and cause of acute complications such as ketoacidosis and hypoglycemia (including ER visits and admissions)
- 4. Prior or current infections, particularly skin, foot, dental, and genitourinary infections
- 5. Specific system history:
  - Symptoms and treatment of chronic eye, kidney or nerve disease
  - Genitourinary and gastrointestinal function
  - Heart, peripheral vascular, foot, and cerebrovascular complications associated with DM
- 6. Use of medications and herbs that may affect blood glucose levels
- 7. Risk factors for CVD, including smoking, hypertension, obesity, dyslipidemia, and family history
- 8. History and treatment of other conditions, including endocrine and eating disorders
- 9. Assessment for mood disorder
- 10. Family history of diabetes and other endocrine disorders
- 11. Cultural, psychosocial, educational, and economic factors that might influence the management of diabetes
- 12. Nutritional habits, weight history and physical activity
- 13. Tobacco, alcohol, and/or controlled substance use
- 14. Contraception and reproductive and sexual history
- 15. Immunization against influenza and pneumococcus

#### Physical Examination

- 1. BMI and waist circumference
- 2. Blood pressure determination, including orthostatic measurements (sitting and standing)
- 3. Inspect eyes for xanthelasmata, cataract or ophthalmoplegia.
- 4. Fundoscopic examination, by an ophthalmologist
- 5. Oral examination (for signs of redness, bleeding, halitosis, accumulation of debris around the teeth, gingival recession with exposed root surfaces, separation of teeth, and tooth mobility)
- 6. Thyroid palpation
- 7. Cardiac examination
- 8. Abdominal examination (e.g., for organomegaly)
- 9. Evaluation of pulses by palpation of dorsalis pedis and posterior tibial; and auscultation of carotids
- 10. Hand/finger examination
- 11. Foot examination
- 12. Skin examination (for acanthosis nigricans, insulin-injection sites, infections, and dyslipidemia)
- 13. Neurological examination
- 14. Signs of diseases that can cause secondary diabetes (e.g., hemochromatosis, pancreatic disease)

#### Laboratory Evaluation

- 1. Average FBS (≥3 readings in the last one week)
- 2. Glycated hemoglobin (A1c)
- 3. Fasting lipid profile (total cholesterol, HDL, triglycerides, and LDL), liver function tests (LFT) (with further evaluation for fatty liver or hepatitis if abnormal)
- 4. Serum creatinine and calculated GFR (eGFR) or creatinine clearance; ± albumin-creatinine ratio (ACR)
- 5. Thyroid-stimulating hormone (TSH), if clinically indicated
- 6. Electrocardiogram in adults
- 7. Urinalysis for ketone, protein, and sediment

#### Etiologic Classification of Diabetes Mellitus

1. Type 1 diabetes (β-cell destruction, usually leading to absolute insulin deficiency)

- 2. Type 2 diabetes (with variable degree of insulin resistance and secretory defect)
- 3. Other specific types:
  - a. Genetic defects of  $\beta$ -cell function
  - b. Genetic defects in insulin action
  - c. Diseases of the exocrine pancreas
  - d. Endocrinopathies
  - e. Drug- or chemical-induced
  - f. Infections
  - g. Uncommon forms of immune-mediated diabetes
  - h. Other genetic syndromes sometimes associated with diabetes
  - i. GDM

#### Assessment of Dyslipidemia

This assessment has to be done in the initial and the annual assessment visits. It might be repeated as needed.

Use CMR Encounter Form no. 2 (CMR-2, available in the original guideline document) to help you in the assessment.

#### Measurement

- Two fasting lipoprotein measurements should be taken to classify the patient's CV risk, prior to initiating drug treatment or intensive lifestyle treatment (see table below). If the total cholesterol level varies more than 30-40 mg/dL (>16%) in the two samples a third sample should be taken and the average of the three samples should be used as the baseline measure.
- Abnormal lipid test results should always be confirmed with a new specimen, within 1–8 weeks later, before beginning or changing therapy.
- The sample should not be performed during stress or acute illness (e.g., recent myocardial infarction [MI], stroke, pregnancy, trauma, weight loss, use of certain drugs); should not be performed on hospitalized patients until 2-3 months after illness.

#### Secondary Dyslipidemia

It must be ruled out through medical, dietary, family history and physical evaluation to determine additional risk factors and any genetic factors (see the table, "Selected Causes of Secondary Dyslipidemia" in the original guideline document). Laboratory testing including FBS, LFT, renal function tests (RFT), TSH (other endocrine function tests if indicated), erythrocyte volume and urinalysis must be done in addition to clinical evaluation.

#### Genetic Disorders

Consider the possibility of a genetic disorder if total cholesterol (TC) is ≥300 mg/dL or if there is a family history of premature CHD.

Table. LDL Cholesterol Goals and Cut Points for Therapeutic Lifestyle Changes (TLC) and Drug Therapy

Risk Category	LDL Goal	LDL Level at Which to Initiate Therapeutic Lifestyle Changes	LDL Level at Which to Consider Drug Therapy
High CV Risk	<100 mg/dL	>100 mg/dL	≥100-130 mg/dL
Moderate CV Risk	<130 mg/dL	>130 mg/dL	≥130-160 mg/dL
Low Added Risk	<160 mg/dL	>160 mg/dL	≥160-190 mg/dL

### Screening for Depression

#### Why Screen for Depression?

- 1. Depression is the most frequently cited psychological disorder associated with diabetes. It is roughly three times more prevalent in those with diabetes (15-20% of people) than in those without diabetes.
- 2. Screening improves the accurate identification of depressed patients in primary health care (PHC).
- 3. Providers may mislabel lack of attention to self-care as non-compliant behavior when, in fact, it may indicate the need to screen for

- depression.
- 4. Early recognition of depression symptoms, prompt treatment, and referral lead to improved self-care and quality of life and decreases clinical morbidity.

#### Symptoms of Depression

The following changes characterize symptoms of depression:

- Decreased ability to cope with changes or challenges in life
- Changes in crying patterns
- Changes in sleeping and eating patterns
- Changes in ability to concentrate
- Changes in sexual desire
- Increased pessimism
- Sense of helplessness
- Thoughts of death or suicide
- Severe sadness
- Loss of interest in usual activities

#### How to Screen for Depression?

- 1. Asking two simple questions about mood and anhedonia may be as effective as using any of the longer screening instruments:
  - a. 'Over the past two weeks have you felt down, depressed, or hopeless?"
  - b. "Over the past two weeks, have you felt little interest or pleasure in doing things?"
- 2. Use formal screening tools, such as the Patient Health Questionnaire (PHQ-9). (See the original guideline document for details on the PHQ-9 test and how to interpret results.)

Identify and monitor severity of depression every 2-4 weeks. Consult a specialist if there is no improvement.

Assessing Renal Function in CMR

Please see the clinical algorithm "Assessing Renal Function in CMR" in the original guideline document.

Foot Care in DM

Please see the clinical algorithm "Foot Care in Diabetes Mellitus" in the original guideline document.

#### Control

Management of Obesity

Management aims to:

- Improve pre-existing obesity-related comorbidities.
- Reduce the future risk of obesity-related comorbidities.
- Improve physical, mental and social wellbeing.

Health care providers need to collaborate with patients to develop eating habits, physical activities and life-long skills to initiate and sustain weight reduction.

A realistic target should be emphasized aiming, initially, at:

- 5-10% reduction of original weight with
- Maximum weekly weight loss of 0.5-1 kg.

#### Physical Activity

- Physical activity refers to all types and intensities of body movement, including activities of daily living.
- Physical activity can be accumulated over the course of the day in multiple small sessions (of at least 10 minutes duration each) and does not need to be performed in a single session.
- Sedentary individuals should build up to their physical activity targets over several weeks, starting with 10-20 minutes of physical activity

every other day during the first week or two of the programme, to minimise potential muscle soreness and fatigue.

• The recommended duration of activity for fitness effects is 30 minutes of moderate-intensity activity (e.g., brisk walking) on most days per week or 60 minutes a day of total physical activity time to control body weight.

Table. Markers of Moderate Intensity Physical Activity

- Increase the rate of breathing
- Increased body temperature
- Comfortable conversation
- Increased heart rate in the range of 55%-70% of age-predicted maximum (220-age)

#### Dietary Advice

- Dietary interventions for weight loss should be calculated to produce a 600 kcal/day energy deficit. This results in a progressive weight loss of 0.5-1 kg per week.
- Dietary advice should be tailored to the preferences of individual patient.
- Emphasize eating breakfast daily and regulate mealtime.
- Encourage patient to read food labels when deciding to purchase food item.
- Provide lower calorie substitution to the patient's usual diet.
- Encourage pre-planning of food and snack.
- Avoid places and situations that encourage weight gain.

#### Behavioral Modifications

Behavioral modifications are useful adjuncts to diet and physical activity. They facilitate assessment of patient motivation and readiness to implement a management plan and take steps to encourage patient treatment.

- Goal setting: allows patients to develop realistic expectations and aim at practical individualized strategies for weight loss.
- Self-monitoring: regular self-weighing.
- Stimulus control: environmental modification to enhance behavior that support weight management.
- Slowing rate of eating
- Problem solving: allows patients to identify the problem, propose options, devise a solution, implement it and evaluate its effectiveness.
- Cognitive restructuring: aiming for increased awareness of one's self and one's weight as well as replacing negative thinking with more
  positive and constructive self-statements.

#### Pharmacological Treatment

- Pharmacological treatment should be considered only after dietary, exercise and behavioral approaches have been started and evaluated.
- Patients considered for pharmacotherapy should have:
  - BMI ≥30 or BMI ≥28 with concomitant obesity-related risk factors or diseases (hypertension, dyslipidemia, CHD, DM-2 or sleep apnea).
  - Therapy continued beyond 3 months only if the person has lost at least 5% of their initial body weight since starting drug treatment.

#### Bariatric Surgery

- Bariatric surgery should be considered on an individual case basis following assessment of risk and benefit in patients who fulfill the following criteria:
  - BMI ≥35 kg/m2.
  - Presence of one or more severe comorbidities which are expected to improve significantly with weight reduction (e.g., severe mobility problems, arthritis, DM-2).
  - Evidence of completion of a structured weight management programme involving diet, physical activity, behavioral and drug
    interventions, not resulting in significant and sustained improvement in the comorbidities.
- Health care professionals should undertake the following in all patients post bariatric surgery:
  - · Simple clinical assessments of micronutrient status (e.g., ask about hair loss, neuropathic symptoms, skin and oral lesions, muscle

weakness) and

- Simple blood tests (e.g., full blood count, calcium, magnesium, phosphate and albumin).
- Calcium and vitamin D supplements (800 IU per day cholecalciferol) should be considered for all patients undergoing bariatric surgery. Baseline calcium and vitamin D should be measured to avoid iatrogenic hypercalcemia.
- Bariatric surgery should not be performed unless systematic follow-up is available and unless the patient has made a commitment to
  participate in such care. As in the preoperative evaluation, postoperative management requires a coordinated approach involving expertise in
  medicine, surgery, psychology, and nutrition.

See the original guideline document for the types of bariatric procedures.

#### **Blood Pressure**

Please see the clinical algorithms "Initial Approach to High Blood Pressure in PHC" and "Blood Pressure Control: Chronic Management" in the original guideline document.

Blood Pressure Control: Choice of a Plan

Choice of a plan for BP control depends on the level of the CVR:

- 1. Stratify the level of CVR using the table in the original guideline document.
- 2. Match the level with its corresponding plan (see the table below).
- 3. Refer to the original guideline document for lifestyle change, for drug treatment, and for glycemic control.
- 4. Refer to appropriate specialist for the management of TOD and CVRD, and continue treatment.

Table. Match CVR with Its Corresponding Plan

Other Risk	Blood Pressure (mmHg)				
Factors and Disease History	Normal: SBP 120- 129 or DBP 80-84	High Normal: SBP 130-139 or DBP 85-89	Grade 1: SBP 140-159 or DBP 90-99	Grade 2: SBP 160-179 or DBP 100-109	Grade 3: SBP >180 or DBP >110
No other risk factors	No blood pressure (BP) intervention	No BP intervention	Lifestyle changes for several months, then drug treatment if BP uncontrolled	Lifestyle changes for several weeks, then drug treatment if BP uncontrolled	Immediate drug treatment and lifestyle changes*
1-2 risk factors	Lifestyle changes	Lifestyle changes	Lifestyle changes for several weeks, then drug treatment if BP uncontrolled	Lifestyle changes for several weeks, then drug treatment if BP uncontrolled	Immediate drug treatment and lifestyle changes*
3 or more risk factors, MetSyn, TOD or diabetes	Lifestyle changes	Drug treatment and lifestyle changes*	Drug treatment and lifestyle changes*	Drug treatment and lifestyle changes*	Immediate drug treatment and lifestyle changes*
CVRD	Drug treatment and lifestyle changes	Immediate drug treatment and lifestyle changes*	Immediate drug treatment and lifestyle changes*	Immediate drug treatment and lifestyle changes*	Immediate drug treatment and lifestyle changes*

Abbreviations: BP, blood pressure; CVRD, cardiovascular or renal disease; DBP, diastolic blood pressure; MetSyn, metabolic syndrome; SBP, systolic blood pressure; TOD, target organ damage

Table. Which Anti-hypertensive Agent to Use?

<sup>\*</sup>Consider the use of statin and aspirin in these risk groups.

Risk Factor/Disease	1st Choice	Second-line Choice	Cautions/Notes
HTN without compelling indications for specific agents	Thiazide diuretics, β-blockers, ACEI, ARBs, or long-acting CCBs (consider ASA and statins in selected patients)	Combination of 1 <sup>st</sup> choice drugs	$\alpha$ -blockers are not recommended as initial therapy. $\beta$ -blockers are not recommended as initial therapy in those >60 years of age. Hypokalemia is avoided by using K <sup>+</sup> -sparing agents in those prescribed diuretic monotherapy. ACEI are not recommended as initial monotherapy in Blacks.
Isolated systolic HTN without compelling indications for specific agents	Thiazide diuretics, ARBs or long-acting DHP-CCBs	Combination of 1 <sup>st</sup> choice drugs	Hypokalemia should be avoided by using $K^+$ -sparing agents in those prescribed diuretics
Diabetes mellitus with nephropathy	ACEI or ARBs	Addition of thiazide diuretics, cardioselective β-blockers, or long-acting CCBs	If serum creatinine level is >2 mg/dL, a loop diuretic should be used as a replacement for low-dose thiazide diuretics if volume control is required.
Diabetes mellitus without nephropathy	ACEI, ARBs or thiazide diuretics	Combination of 1 <sup>st</sup> choice drugs or addition of cardioselective β-blockers ± long-acting CCBs	
Metabolic syndrome	ACEI or CCB	ARB	
Atrial fibrillation	Recurrent AF: ACEI, ARB	Permanent AF: β- blocker, NDHP- CCB	
Angina	β-blockers and ACEI	Long-acting CCBs	Avoid short-acting nifedipine
Established atherosclerotic disease	ACEI added to other therapy		
Previous myocardial infarction	β-blockers and ACEI	Combination of additional agents	
Heart failure	ACEI, β-blockers and spironolactone	ARBs; thiazide or loop diuretics, as additive therapy	Avoid DHP-CCBs (diltiazem, verapamil)
Previous CVA or TIA	ACEI/diuretic combination		Blood pressure reduction reduces recurrent cerebrovascular events
Chronic kidney disease; microalbuminuria	ACEI (diuretics as additive therapy)	ARB	Avoid ACEIs in bilateral renal artery stenosis
LVH	ACEI, ARBs, long- acting CCBs, thiazide diuretics (β-blockers for those under 60 years)		Avoid hydralazine and minoxidil

Peripheral Risk arterial disease	ACEI added to other 1st Choice therapy	CCB Second-line Choice	Avoid β-blockers with severe disease Cautions/Notes
Factor/Disease Dyslipidemia	No special		
	recommendation		
Elderly (isolated systolic HTN)	Diuretic; CCB		No definite evidence of an increase in risk of aggressive treatment (a J-curve) unless diastolic blood pressure (DBP) is lowered to <55 or 60 mmHg by treatment
Lactating	Propranolol and labetalol are preferred if a β-blocker is indicated		Diuretics may reduce milk volume.
Pregnancy	Methyldopa, labetalol, CCB		ACEIs and ARBs should be avoided (associated with adverse fetal and neonatal renal effects.)
Smokers			Interferes with the beneficial effects of $\beta$ -blockers
Bronchospasm; 2 <sup>nd</sup> /3 <sup>rd</sup> degree heart block			β-blockers should generally be avoided
Hyperthyroidism; anxiety; sinus tachycardia	β-blockers		

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; AF, atrial fibrillation; ARB, angiotensin receptor blocker; ASA, aspirin; CCB, calcium channel blocker; CVA, cerebrovascular accident; DHP-CCB, dihydropyridine calcium channel blocker; HTN, hypertension; K+, potassium; LVH, left ventricular hypertrophy; NDHP-CCB, non-dihydropyridine calcium channel blocker; TIA, transient ischemic attack

Change of Anti-HTN Medications

#### General Principles

Changing therapy risks new side effects and it may take time to re-establish adequate control of blood pressure. A change of therapy is unlikely to be appropriate in patients on three or more antihypertensive drugs.

Once a hypertensive drug therapy is initiated, most patients should return for follow-up and medication adjustments at least at monthly intervals until BP goal is reached.

If blood pressure goals are not met the clinician has three options for subsequent therapy:

- 1. Increase the dose of the initial drug toward maximal levels
- 2. Substitute an agent from another class
- 3. Add a second drug from another class

#### Individualized Drug Selection Is Based on Several Principles

- 1. If the initial response to one drug is:
  - Adequate: continue the same drug
  - Partial: increase the dose or add a second drug of a different class
  - Little: substitute another single drug from a different class
- 2. Consider low-dose diuretic use early or as a first addition.
  - Consider loop diuretic agents instead of thiazide or thiazide-like diuretics when creatinine is >2.0 mg/dL or eGFR <30.
- 3. Do not combine two drugs of the same class.
- 4. Combine agents at medium doses. It can be more effective than a high-dose single agent. In addition, it can result in fewer side effects.
- 5. Combination is more effective if a medicine from column 1 is combined with another from column 2.

Column 1	Column 2
<ul><li>Diuretics</li><li>Calcium channel blockers</li></ul>	<ul> <li>Angiotensin-converting enzyme (ACE) inhibitors</li> <li>Angiotensin receptor (AR) blockers</li> <li>β-blockers</li> </ul>

#### Resistant Hypertension

Hypertension may be termed resistant to treatment, or refractory, when a therapeutic plan that has included attention to lifestyle measures and the prescription of at least three drugs in adequate doses has failed to lower systolic and diastolic blood pressure sufficiently, after 6 months of follow-up. In these situations, referral to a specialist should be considered, as resistant hypertension is known to be often associated with target organ damage.

#### White Coat Hypertension

White-coat HTN (WCH) or "isolated office HTN" is a persistent elevation of BP in the physician's office with normal BP at home or by ambulatory BP monitoring. Once suspected, BP must be evaluated using home or ambulatory measurement. See the original guideline document for a chart that summarizes the approach recommended for managing WCH.

#### Hyperglycemia and Hypoglycemia

See the clinical algorithms "Initial Management of Symptomatic Hyperglycemia" and "Glycemic Control: Chronic Management" in the original guideline document.

See the clinical algorithms "Management of Hypoglycemia" in the original guideline document.

#### Use of Oral Hypoglycemic (OHG) Agents

- Once an OHG drug therapy is initiated, most patients should return for follow-up and medication every 1-2 weeks until glycemic goal is reached.
- If glycemic goals are not met the clinician has three options for subsequent therapy:
  - 1. Increase the dose of the initial drug toward maximal levels
  - 2. Substitute an agent from another class
  - 3. Add a second drug from another class
- Start metformin use early or as a first addition, unless contraindicated. Begin with low dose and titrate gradually, to avoid gastrointestinal (GI) intolerance
- Do not combine two drugs of the same class
- Combine agents at medium doses. It can be more effective than a high-dose single agent. In addition, it can result in fewer side effects

#### Assessment of Glycemic Control

#### Table. Levels of Glycemic Control

Target Test
A1c <7%
Average fasting blood sugar (FBS) 90–130 mg/dL (5 - 7.2 mmol/L)
Average 2 hour-postprandial blood sugar (PPBS) <180 mg/dL (10 mmol/L)
Average bedtime glucose <120 mg/dL (6.7 mmol/L)

#### Glycemic control is best assessed by A1c. Please note that:

- 1. Hemoglobinopathies, hemolysis and blood loss interfere with its accuracy.
- 2. Fructosamine (reflects glycemic control in the last 1-2 weeks) might be used instead, if available.
- 3. Average of multiple readings of FBS is a useful tool in achieving glycemic control (done daily or alternately). However, it reflects control

over the measurement period only.

#### Limitations on use of A1c in DM

- In people who have hemoglobin variants such as HbS (sickle cell trait), some A1c tests give falsely high or low readings that can lead to the over-treatment or under-treatment of diabetes.
- Laboratories use many different methods for measuring A1c, but some of these methods can give inaccurate results when the patient has a hemoglobin variant such as sickle cell trait.
- The National Glycohemoglobin Standardization Program in America (www.ngsp.org ) provides information about which assay methods are appropriate for patients with hemoglobinopathies.
- Shortened Erythrocyte Survival: Any condition that shortens erythrocyte survival or decreases mean erythrocyte age (e.g., recovery from
  acute blood loss, hemolytic anemia, transfusion, HbSS, HbCC, HbSC) will falsely lower HbA1c test results regardless of the assay
  method used.

#### Insulin Therapy in T2DM: General Guideline

- Type 2 DM is a progressive disease in which \( \beta\)-cell function deteriorates. Most patients will eventually need insulin.
- Early initiation of insulin would be a safer approach for individuals presenting with weight loss, severe symptoms and RBS >250 mg/dL (14 mmol/L).
- Insulin might be added to the oral regimen if glycemic control is not achieved, after the use of two different classes. This has to be done by an expert physician.

Table: Types of Insulin Regimen

	Regimen		
Characteristics	Basal-Only	Mixed	Basal-Bolus
Blood Sugar Pattern	Increased FBS + minimally increased PPBS	Any FBS + increased PPBS	Any blood sugar level
Diet Pattern	Small, regular meals	Isocaloric meals or larger lunches	Any diet pattern
Lifestyle	Reluctance to have MDI	Consistent daily routine, reluctance to do MDI	Erratic schedule, motivated to achieve tight glycemic control
Monitoring	Fasting	Fasting and pre-supper (if twice daily)	Before meals and bedtime
Insulin Types	NPH - Glargine	NPH+Regular	Glargine+Rapid

Abbreviations: FBS, fasting blood sugar; MDI, multi-dose insulin; NPH, neutral protamine Hagedorn; PPBS, postprandial blood sugar

See the original guideline document for a table of the insulin types, onset time, peak time, and effective duration.

- Preferably begin with human NPH insulin, taken at bedtime or twice daily according to need.
- Consider, as an alternative, using insulin glargine for:
  - Persons who experienced significant nocturnal hypoglycemia, while using neutral protamine Hagedorn (NPH) insulin.
  - Persons who require assistance from a carer or health care professional to administer their insulin injections.
  - Persons whose lifestyle is significantly restricted by recurrent symptomatic hypoglycemic episodes.
  - Persons who would otherwise need once daily basal insulin injections in combination with oral glucose-lowering medications.

#### Is the PHC Setting Ready for Insulin Therapy?

When starting insulin therapy, use a structured programme employing active insulin dose titration that includes:

- 1. Structured education by a Certified Diabetes Educator.
- 2. Continuing easy-access support (including telephone).
- 3. Frequent self-monitoring.
- 4. Dietary understanding and review.

- 5. Management of hypoglycemia.
- 6. Management of acute changes in blood sugar control.
- 7. Support from an appropriately trained and experienced physician.

#### Is the Patient Fit and Ready for Insulin Therapy?

- 1. New patients with extreme hyperglycemia (FBS >250 mg/dL [14 mmol/L]).
- 2. Patients who are unable to achieve A1c goals using oral agents.
- 3. Patients educated by a certified diabetes educator to:
  - Ensure proper administration and understanding of the insulin regimen.
  - Discuss the benefits and risks of insulin therapy.
- 4. Patient and care giver agree on starting insulin therapy.

#### Hyperlipidemia

Please see the clinical algorithm "Lipid Control & Statin Therapy" in the original guideline document.

Lipid Lowering Agents

#### Notes on the Use of Statins

- 1. Bedtime or evening dose of statin is more effective (higher cholesterol synthesis).
- 2. Dosage adjustments should not be made more often than every 4 weeks after a fasting lipid profile.
- 3. If patients are intolerant to a statin, clinicians are encouraged to have the patient try the other statins in reduced doses before ruling out all statins.
- 4. If patients are unable to take a statin, then fibric acids and other lipid lowering agents may be used.
- 5. Safety Considerations

DO

- Check baseline renal function and TSH prior to initiating statin therapy.
- Check alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels prior to prescribing a statin and prior to any planned increase in statin dose.
- Consider the potential for drug-drug interactions when prescribing statins. Vitamin E intake may reduce the benefit of statins.
- Counsel patients to discontinue statin therapy during a short course of a macrolide antibiotic (erythromycin, azithromycin, and clarithromycin).
- Be alert for patient characteristics that may increase the risk for myopathy during statin therapy, such as advanced age, renal or liver impairment, diabetes with evidence of hepatic fatty changes, hypothyroidism, surgery, trauma, ischemia-reperfusion, debilitated status, heavy exercise.
- Provide patient education regarding recognition and reporting of symptoms of myopathy during statin therapy.
- Suspect myopathy when a statin-treated patient complains of unexplained, generalized muscle pain, tenderness, or weakness. Joint pain, nocturnal leg cramps, or localized pain are not symptoms of myopathy.
- Assess for signs of dehydration or renal compromise in patients with myopathy.
- Check creatine kinase (CK) levels when a patient reports symptoms of myopathy.
  - $\bullet~$  If CK levels are less than 5 times upper limit of normal, repeat measurement in 1 week.
  - If CK levels are elevated to 5 times upper limit of normal or greater, discontinue statin therapy and monitor serum CK levels.
- Consider referral for patients requiring combination lipid-lowering therapy.
   DON'T
- Prescribe high-dose statin therapy for elderly patients and patients with renal insufficiency, or in combination with fibrates.

#### Aspirin Therapy

- ASA reduces the risk of a cardiovascular event by about 25% over 5 years, in both sexes.
- The decision to use aspirin should be based on a balance of the risks and benefits for each person, taking into account their absolute risk of an event.

#### ASA Indications

• Very High CV Risk:

- Commence low-dose ASA (75-150 mg).
- High CV Risk:
  - Commence low-dose ASA (75-150 mg) unless contraindicated. Low-dose ASA is as effective as higher daily doses and may be
    associated with less side effects.
- Low-Medium CV Risk:
  - The risk of significant adverse effect (bleeding) outweighs the benefits of ASA for the prevention of CVD.

#### ASA Contraindications

- ASA allergy
  - Patients with documented ASA allergy may consider clopidogrel (75mg/day) as an alternative.
- ASA intolerance
- Uncontrolled blood pressure
- Active peptic ulceration
- Any major bleeding risk

#### Adverse Effects

- Bleeding is the most serious side effect:
  - Intracranial bleeding: absolute excess risk ~2/1000 people treated/year.
  - Extracranial bleeding: absolute excess risk ~1-2/1000 people treated/year. Most are not fatal.
  - Upper GI bleeding/perforation: regular ASA <300 mg/day is associated with a two-fold increased risk.
- Notes on monitoring adverse effects:
  - Monitor stool for occult blood or change in color.
  - Monitor hemoglobin ± hematocrit for drop due to bleeding or hemolysis (especially in glucose-6-phosphate dehydrogenase [G6PD] deficiency).
  - Monitor bilirubin for rise due to hemolysis (in G6PD deficiency).

#### Immunization & Opportunistic Preventive Care

#### Influenza Vaccine

- Annual vaccination is recommended for all adults without contraindications in the following groups and their household contacts:
  - Persons aged 50 years and older
  - Women who will be pregnant during the influenza season
  - Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus)
  - Persons who have immunosuppression
- Annual vaccination is recommended for all health-care personnel.

#### Pneumococcal Vaccine

- Vaccinate all previously unvaccinated adults age 65 years and older.
- Vaccinate all adults who smoke cigarettes, have chronic CVD (e.g., congestive heart failure, cardiomyopathy), chronic pulmonary disease (e.g., COPD, emphysema, adults with asthma), DM, chronic renal failure or sickle cell disease.
- Revaccinate after 5 years those above 65 years and at high risk of serious pneumococcal disease.

#### Oral & Dental Examination

- Diabetic persons are more susceptible to oral infections such as periodontal disease, particularly if not controlled.
- The presence of active periodontitis can, in turn, impair glycemic control and increase the risk of developing systemic complications of diabetes, particularly cardiovascular disease and stroke.
- People with DM must have a routine visual inspection of their gums and teeth for signs of periodontal disease at diagnosis and during each diabetes-focused visit, by the PHC physician.
- A dental exam is recommended at diagnosis and then every 6 months if dentate or every 12 months if edentate.
- Refer a person who is suspected of having periodontal disease to a dentist to ensure early and prompt diagnosis and treatment.
- Signs of periodontal disease:
  - Red, sore, swollen, receding, or bleeding gums

- Loose or sensitive teeth; separation of teeth
- Halitosis (bad breath)
- Accumulation of food debris or plaque around teeth

#### Mammogram

- Evidence supports a modest association between type 2 diabetes and the risk of breast cancer, which appears to be more consistent among postmenopausal than among premenopausal women.
- Screening mammography is recommended for all women aged 50 to 74 years, every 2 years. Consequently, it is wise to have mammogram done for all eligible population, and diabetic ladies in particular.

### Clinical Algorithm(s)

The original guideline document contains clinical algorithms for:

- Case Identification (cardiovascular risk)
- Chronic Management
- Assessing Renal Function in CMR
- Foot Care in Diabetes Mellitus
- · Obesity Management
- Initial Approach to High Blood Pressure in PHC
- Blood Pressure Control: Chronic Management
- White Coat Hypertension
- Initial Management of Symptomatic Hyperglycemia
- Management of Hypoglycemia
- Glycemic Control: Chronic Management
- Insulin Therapy: General
- Insulin Therapy: Suggested Regimen
- Lipid Control & Statin Therapy
- Lifestyle Management (in Arabic only)
- CMR Patient Recall

## Scope

## Disease/Condition(s)

- Cardiovascular disease (CVD)
- Type 2 diabetes mellitus (T2DM)

## Other Disease/Condition(s) Addressed

- Depression
- Dyslipidemia
- Hypertension
- Obesity

## Guideline Category

Counseling

Diagnosis

Evaluation
Management
Prevention
Lisk Assessment
Screening
Preatment Preatm
Clinical Specialty
Cardiology
Endocrinology
Family Practice
nternal Medicine
Preventive Medicine
ntended Users
Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Nurses
Physician Assistants
Physicians
sychologists/Non-physician Behavioral Health Clinicians
Guideline Objective(s)
<ul> <li>To provide a comprehensive approach to the management of cardiometabolic risk (CMR) factors in non-pregnant adults</li> <li>To include nutrition therapy, physical activity recommendations, pharmacologic therapy, self-management, as well as prevention and</li> </ul>

- diagnosis of CMR-associated complications
- To provide suggestions to the management of the delivery system, the clinical information and the quality of care
- To assist clinicians by providing a framework for the evaluation and treatment of CMR patients

## **Target Population**

- Non-pregnant adult patients
- Individuals at increased risk for cardiovascular disease and type 2 diabetes mellitus, including:
  - Individuals at age of 45 years and over (preferably, at age of 35 for male)
  - All obese individuals
  - All hypertensive, diabetic, and dyslipidemic individuals

#### Interventions and Practices Considered

Screening/Diagnosis/Risk Assessment for Cardiometabolic Risk

- 1. Family and patient medical history
- 2. Physical examination: body mass index (BMI), waist circumference, blood pressure
- 3. Laboratory tests: lipid profile, triglycerides, glucose; fasting blood sugar, serum uric acid, serum creatinine and glomerular filtration rate estimation (eGFR), serum potassium and sodium, hemoglobin and hematocrit, urinalysis (including microalbuminuria assessment), C-reactive protein
- 4. Electrocardiogram
- 5. Screening for depression
- 6. Assessment of cardiovascular (CV) risk

#### Management/Treatment

- 1. Lifestyle counseling and goal setting, including smoking cessation
- 2. Annual assessment: targeted history and physical exam, CV and cerebrovascular assessment, renal assessment, foot exam and risk assessment for diabetes patients, dilated eye exam, re-estimation of CV risk, mood assessment
- 3. Specialist referral
- 4. Frequency of follow-up for various conditions
- 5. Drug therapy (anti-hypertensive agents, anti-glycemic agents, dyslipidemic agents [particularly statins]) alone or in combination
- 6. Aspirin therapy
- 7. Coordination of care
- 8. Self-management

### Major Outcomes Considered

- Changes in laboratory markers of cardiometabolic risk
- Changes in blood pressure
- Hospitalization or emergency room visit rates
- Side effects of treatment
- Adherence to nonpharmacological and pharmacological treatment
- Morbidity and mortality

## Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

In general, the evidence analyses used for the original guideline were published, evidence-based guidelines concerned with the screening, management and prevention of hypertension (HTN), diabetes mellitus (DM), dyslipidemia and obesity, from the year 2001 to 2010.

However, members of the group were asked to identify any more recent publications relevant to the section of the guideline allotted to them. Members of the group were encouraged to review details of papers referred to in the published guidelines.

Key evidence-based reviews and meta-analyses are also referenced. National guidelines were reviewed and matched with particular attention to the quality measures and information management.

• PubMed
Goggle Scholar (http://Scholar.goggle.com
Saudi Medbase
National Guideline Clearinghouse (http://guideline.gov     ).
One or more of the following key-words were used:
Primary Care
<ul> <li>Diabetes, Hypertension, Dyslipidemia, Obesity, Cardiovascular Risk</li> </ul>
Screening, Lifestyle management
Encounter form, decision-making, implementation tool, guideline development, chronic care management, quality management
Primary care-oriented materials only were selected.
Number of Source Documents
Not stated
Not stated
Methods Used to Assess the Quality and Strength of the Evidence
Expert Consensus
Rating Scheme for the Strength of the Evidence
Not applicable
Methods Used to Analyze the Evidence
Review
Review of Published Meta-Analyses
Description of the Methods Used to Analyze the Evidence
Not stated
INOU STATEGU
Methods Used to Formulate the Recommendations
Expert Consensus

For the 2011 update, the following databases were searched:

## Description of Methods Used to Formulate the Recommendations

The guideline development involved a broad group of primary health care professionals, including physicians, nurse practitioners, specimencollection nurses, screening nurses, pharmacists, educators and dietitians.

Within the group, a number of people had considerable experience in guideline development and in health-care administration, as well as in primary health care development and delivery of service.

The recommendations of the guideline are concordant with those made by most international guidelines, with some minor adaptations to the national health care system. The process of adaptation is concordant, as well, to that described by the Canadian Medical Association (Adapte,



The steps to formulate the recommendations are provided in the original guideline document in the algorithm entitled, "Outline of CCCQI CMR Guideline Development."

### Rating Scheme for the Strength of the Recommendations

Not applicable

### Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

The guideline was evaluated, repeatedly, by the developing team, using the Appraisal of Guidelines Research & Evaluation (AGREE) instrument (http://www.agreetrust.org \_\_\_\_\_\_).

Each review undergoes peer review before submission to the Steering Committee for review. The Steering Committee develops a consensus statement that considers the clinical evidence, applicability, cost effectiveness and cultural values.

## Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

In general, published evidence-based guidelines were used as the basis for the recommendations.

## Benefits/Harms of Implementing the Guideline Recommendations

#### **Potential Benefits**

Appropriate cardiometabolic risk management for individuals with increased risk for cardiovascular disease and type 2 diabetes mellitus

#### **Potential Harms**

Bleeding is the most serious side effect of aspirin (ASA).

- Intracranial bleeding: absolute excess risk ~2/1000 people treated/year.
- Extracranial bleeding: absolute excess risk ~1-2/1000 people treated/year. Most are not fatal.
- Upper gastrointestinal (GI) bleeding/perforation: regular ASA <300 mg/day is associated with a two-fold increased risk.

See the tables, "Which Anti-Hypertensive Agent to Use?", "Anti-Hypertensive Agents", "Anti-Glycemic Agents," and "Dyslipidemic Agents" in the "Major Recommendations" field and in the original guideline document for potential side effects of recommended agents.

### Contraindications

#### Contraindications

- Aspirin (ASA) contraindications
  - ASA allergy
  - ASA intolerance
  - Uncontrolled blood pressure
  - Active peptic ulceration
  - Any major bleeding risk
- An annual influenza vaccination is recommended for all adults without contraindications in the following groups and their household contacts:
  - Persons aged 50 years and older
  - Women who will be pregnant during the influenza season
  - Persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, cognitive, neurologic/neuromuscular, hematological or metabolic disorders (including diabetes mellitus)
  - Persons who have immunosuppression

See the tables, "Which Anti-Hypertensive Agent to Use?," "Anti-Hypertensive Agents," "Anti-Glycemic Agents", "Lipid Lowering Agents," and "Dyslipidemic Agents" in the "Major Recommendations" field and in the original guideline document for contraindications to using recommended agents in patients with various co-existing medical conditions.

## **Qualifying Statements**

### **Qualifying Statements**

- This Cardiometabolic Risk (CMR) Guideline is designed to assist clinicians by providing a framework for the evaluation and treatment of CMR patients, and is not intended to replace a clinician's judgment.
- The recommendations of the guideline are concordant with those made by most international guidelines, with some minor adaptations to the national health care system.

## Implementation of the Guideline

## Description of Implementation Strategy

#### Priority Aims

A multifactorial intervention targeting hyperglycemia and cardiovascular risk factors is the most effective approach to control the disease and prevent complications. Both individual measures of care as well as comprehensive measures of performance on multifactorial interventions are recommended.

- 1. Decrease the percentage of patients with poorly controlled blood sugars, blood pressure (BP) and low-density lipoprotein (LDL).
- 2. Decrease the percentage of cardiovascular risk.
- 3. Increase the percentage of patients for whom recommended workup (including glycated hemoglobin [A1c] and LDL) are done.
- 4. Increase the percentage of patients for whom recommended treatment goals are met.
- 5. Improve self-management skills, including the adoption of healthy lifestyle and weight reduction.
- 6. Increase the percentage of patients for whom cardiovascular risk (CVR) is estimated.
- 7. Increase the percentage of general patients for whom BP is measured in every visit.

- 8. Increase the percentage of general patients for whom body mass index (BMI) is calculated once a year at minimum
- 9. Increase the percentage of general patients of age ≥45 years and older or with BMI >30 screened for cardiometabolic risk (CMR).
- 10. Increase the percentage of hypertensive diabetic patients for whom an angiotensin-converting enzyme inhibitor (ACEI) was prescribed.
- 11. Increase the percentage of high CVR patients for whom aspirin was prescribed.
- 12. Increase the percentage of high CVR patients for whom statin was prescribed.

#### Training Plan

Training modules have been developed to orient and train health care providers on the required skills to manage cardiometabolic risk. These include competency exams and certificates to ensure acquisition of needed skills.

#### Expected Barriers in Implementation

Few barriers may hamper the dissemination and implementation of this guideline. These include the difficulty in affording stable trained staff assigned for chronic care; laboratory tests such as albumin-creatinine ratio (ACR), A1c and lipid profile; medications such as statin, apparatus such as proper cuffs, tuning forks and sensory monofilaments; and stationeries such as guideline printings, educational material and encounter forms.

Good coordination with ophthalmologist and dentist for routine eye and oral screening is crucial. In addition, barriers for effective referral to specialist must be considered, including cardiology, nephrology, diabetology and psychiatry.

#### Quality Measures

The purpose of the guideline is to control CMR. However, producing the guideline alone is insufficient to address this goal. There must be a continuous process of implementation involving education and audit. For this purpose, many quality measures are used nationally and worldwide. For this purpose a dedicated team has been assigned for this task. Many efforts have been paid to review and appraise the commonly used measures. Please refer to the original guideline document for more information on quality measures.

### Implementation Tools

Audit Criteria/Indicators

Chart Documentation/Checklists/Forms

Clinical Algorithm

Foreign Language Translations

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### IOM Care Need

Getting Better

Living with Illness

Staying Healthy

#### **IOM Domain**

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Guideline Developing Team. Cardiometabolic risk management guidelines in primary care. Qatif (Saudi Arabia): Qatif Primary Health Care; 2011. 124 p.

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2008 (revised 2011)

### Guideline Developer(s)

Qatif Primary Health Care - National Government Agency [Non-U.S.]

### Source(s) of Funding

Qatif Primary Health Care

#### Guideline Committee

Practice Guidelines Writing Committee

## Composition of Group That Authored the Guideline

Committee Members: Bader Almustafa, MD (Chief Editor); Nada Alfaraj, MBBS; Aamal Almobarak, BSc; Nawal Al-Eid, BSc, RN; Farha Almarhoon, RN, RE

#### Financial Disclosures/Conflicts of Interest

No financial or conflict of interest matters to disclose.

### Guideline Endorser(s)

Saudi Hypertension Management Society - Disease Specific Society

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Quality Improvement Team in Chronic Care (CCQI). Cardiometabolic risk management in primary care. Qatif (Saudi Arabia): Qatif Primary Health Care; 2008. Various p.

### Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available by request. E-mail: cccqi.ksa@gmail.com.

### Availability of Companion Documents

The following is available:

Cardiometabolic risk management. Pocket guideline. Qatif (Saudi Arabia): Qatif Primary Health Care. 2011. 2 p. Electronic copies: Not
available at this time.

Print copies: Available by request. E-mail: cccqi.ksa@gmail.com.

Additionally, a variety of implementation tools are available in the original guideline document, including blood pressure measurement standards, audit criteria, encounter forms, and register diaries.

#### Patient Resources

Several Arabic-language patient educational tools and pamphlets are available in the original guideline document.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

#### **NGC Status**

This NGC summary was completed by ECRI Institute on February 12, 2009. The information was verified by the guideline developer on February 14, 2009. This summary was updated by ECRI Institute on June 27, 2011 following the U.S. Food and Drug Administration advisory on Zocor (simvastatin). This summary was updated by ECRI Institute on September 27, 2011. The updated information was verified by the guideline developer on December 9, 2011. This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisories on Statin Drugs and Statins and HIV or Hepatitis C drugs. This summary was updated by ECRI Institute on April 15, 2016 following the U.S. Food and Drug Administration advisory on Metformin-containing Drugs.

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